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United States Environmental Protection Agency
401 M St., SW
Washington, D.C., 20460

NATIONAL AMBIENT AIR QUALITY STANDARDS PROPOSED DECISIONS ON PARTICULATE MATTER AND OZONE

SUBMISSIONS FILED BY:

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1. INTRODUCTION

Ontario welcomes the opportunity to provide submissions to the United States Environmental Protection Agency concerning its Proposed Decisions related to particulate matter and ozone. We recognize that the proposal to implement new standards for particulate matter and ozone is an important and complex scientific and public policy initiative.

Carol Browner, the United States Environmental Protection Agency Administrator, has said that the ozone and particulate matter standards are "one of the most important decisions I will make to protect public health in this country".[1] The decision will have important impacts on public health in Ontario as well, because Ontario receives significant levels of transboundary air pollution from the United States. Particulate matter and the ozone precursors, nitrogen oxides and volatile organic compounds, are important elements in the transboundary pollution that Ontario receives from the United States. During hot summer days, more than 50 per cent of the the ozone affecting Ontario comes from sources in the United States.

Ontario's interest in this initiative is a direct reflection of its interest in the quality of the airshed that we share with American states. The linkage of our mutual interests in these pollutants and their adverse health and environmental effects is implicit in the Environmental Protection Agency's Proposed Decision documents themselves. The Proposed Decision for particulate matter contains two specific references to Canada. Similarly, the Proposed Decision for ozone contains four specific references to Canada.

In view of the transboundary pollution impacts on Ontario from particulate matter and ozone, Ministry scientists have reviewed the Proposed Decisions in some detail. Ontario's position on the Proposed Decisions, the basis for our interest in this initiative, and our scientific analysis are set out below.

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[1] Air and Waste Management Association Magazine for Environmental Managers, January 1997, page 6.

2. ONTARIO'S POSITION ON THE PROPOSED DECISIONS

It is Ontario's submission that the United States Environmental Protection Agency should implement more stringent standards than those proposed. Specifically, the position of the Province of Ontario with respect to the Proposed Decisions for particulate matter and ozone is as follows:

2.1 Proposed Decision on Particulate Matter Docket Number A-95-54

PM_{10}

Ontario respectfully requests that the United States Environmental Protection Agency adopt a more stringent standard for PM_{10} while efforts are underway to move to a $PM_{2.5}$ standard.

$PM_{2.5}$

Ontario respectfully requests that the United States Environmental Protection Agency adopt a more stringent standard for $PM_{2.5}$, at the lower end of the range recommended by the Agency's scientists.

2.2 Proposed Decision on Ozone Docket Number A-95-58

Ontario respectfully requests that the United States Environmental Protection Agency adopt more stringent primary and secondary standards for ozone, implement a concentration-based form for the primary standard set at the lower end of the proposed range, and reduce the rounding convention from 0.005 to 0.001 ppm.

3. ONTARIO'S INTEREST IN THE PROPOSED DECISIONS

3.1 Ontario's Perspective

The Province of Ontario, Canada is located in the Great Lakes basin, immediately north of the Canada-United States international boundary. Ontario shares the Great Lakes basin with eight American states: Minnesota, Wisconsin, Illinois, Indiana, Michigan, Ohio, Pennsylvania and New York. Ontario is Canada's most populated province. The majority of the population live in the southern portions of the Province, close to the Great Lakes and the international border.

Ontario shares a common airshed with many American states, primarily the Great Lakes states and other states adjacent to them. The emission of pollutants in one area can affect air quality in the whole airshed. Accordingly, Ontario is vitally interested in initiatives in the United States related to atmospheric emissions of particulate matter and the gaseous precursor compounds that react in sunlight to produce ground level ozone. Ontario's concern rests primarily on the following facts:

- Ontario is geographically located adjacent to the United States and shares a common airshed.

- The prevailing winds are frequently from the south and the southwest: that is, from the United States to Ontario.

- The chemicals involved in the formation of particulate matter and ozone, including the gaseous precursors nitrogen oxides ("NOx"), volatile organic compounds ("VOC"), and sulphur dioxide (SO_2), are capable of being transported over long distances.

- American states play a significant role in the emission of pollutants into the common airshed. The total emissions in the eight Great Lakes States of PM_{10}, NOx, VOC, and SO_2 are much higher than the corresponding total emissions in Ontario. Table 1 sets out emissions of these pollutants in 1990.

Table 1 Comparison of 1990 Emissions of PM_{10} and Gaseous Precursor Compounds of Ozone and Particulate Matter

(in thousand metric tonnes)

	PM_{10}	NOx	VOC	SO_2
U.S. Great Lakes States[2]	9,232	5,791	5,334	8,208
Ontario[3]	760	653	868	1,192

Ontario acknowledges that higher emissions of these pollutants in the American states reflect much greater population levels and higher levels of economic activity. Ontario also recognizes that not all of the emissions of these pollutants from American sources have transboundary implications. Nevertheless, the combined effects of geography, chemistry, and weather patterns compel Ontario's interest in this initiative to implement new standards for particulate matter and ozone in the United States.

No level of government can change geography, chemistry or the weather. But governments can work together to ensure that their respective jurisdictions produce less of these substances which affect our common airshed and cause harm to human health and the environment. The purpose of Ontario's submission is to ensure that the United States Environmental Protection Agency is aware of our concerns and to urge it to adopt tougher atmospheric standards for particulate matter and ozone than it has proposed.

3.2 U.S. Transboundary Pollution Impacts in Ontario

It is very clear that the transboundary movement of particulate matter and the gaseous precursors of ozone, NOx and VOC, have major health and environmental impacts in Ontario. Some of the impacts are set out below:

- Scientific modelling by Ministry experts shows the significance of transboundary pollution impacts on ozone concentrations in Ontario. The modelling demonstrates that emissions from the United States typically contribute 50% - 70% of the ozone caused by human activities. On hot summer days, more than 50% of the ozone affecting Ontario comes from sources in the United States.

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2 U.S. EPA, National Inventory 2-Tier Report Generator Database, May 1995. (includes emissions from Minnesota, Wisconsin, Illinois, Indiana, Michigan, Ohio, Pennsylvania and New York)

3 Ontario Ministry of Environment and Energy, Fast Reference Emission Document Version 3, May 1996

- Photochemical model simulations with comprehensive three dimensional Eulerian models over domains which include southern Ontario have been performed by a number of groups. For the Canadian NOx/VOC Management Plan, model simulations for the Windsor/Quebec City corridor have been carried out by groups at the Ontario Ministry of Environment and Energy, Environment Canada and Ontario Hydro. The Ozone Transport Assessment Group ("OTAG") is currently assessing a number of NOx/VOC emission reduction strategies and scenarios. All of these model simulations have shown that southern Ontario is affected both by regionally elevated ozone concentrations resulting from precursor emissions over a broad area, and by plumes of even higher ozone concentrations originating from precursor emissions in urban areas or heavily industrialised regions. Southern Ontario is often affected by transboundary plumes from the Greater Detroit area, the Cleveland/Ohio Valley area, and from Chicago. The impact of U.S. sources on ozone in southern Ontario has also been demonstrated by analyses of ground level ozone monitoring measurements. Specifically, these analyses have shown that during summer-time ozone episodes, occurring in hot, hazy, humid conditions, with winds from the southwest, more than 50% of the ozone can be attributed to U.S. sources.

- Ozone modelling studies carried out in Canada and the United States have shown the benefits of reducing NOx and VOC emissions on ozone in the United States and in Ontario. OTAG recently carried out a modelling study examining the effects of various NOx and VOC emission reductions on ozone levels. If NOx and VOC emissions in the United States are reduced by about 40 and 20% respectively, high ozone levels in Ontario would decrease by about 15 to 25% for the episodes modelled. Accordingly, Ministry scientists believe that emission controls developed to meet more stringent standards will lead to even greater improvements in air quality in Ontario.

- Ozone problems within Ontario cannot be solved only by actions within the Province. If all of the NOx and VOC emitted in Ontario from human sources were removed, Ontario would still have difficulty meeting its ozone objective. That is, the NOx and VOC compounds transported into Ontario from the United States are capable, on their own, of causing Ontario's ozone objective to be frequently exceeded. Accordingly, much of the ground level ozone in Ontario is beyond the direct control of the Province and its residents because it originates in the United States.

- In the summer of 1995, Ontario's hourly ozone objective of 80 parts per billion was exceeded 600 times, as measured at 10 monitoring stations in southwestern Ontario. There were four days in the summer of 1995 when

Ontario suffered ozone level of 125 parts per billion or higher. These occurred in southwestern Ontario and were directly related to transboundary air flows from neighbouring states in the United States.

- The state of the science for particulate matter is not as well advanced as for ozone. However, scientists believe that particulate matter, especially the finer particles, including $PM_{2.5}$, are susceptible to long range transport. In an analysis carried out under the acid rain program, it was found that United States sources contributed 60 - 80% of the sulphur found in precipitation at sites in southern Ontario. Ministry scientists expect a similar proportional contribution from United States sources to sulphate particulate matter.

- A seven year study (1988-1994) of daily measurements of PM_{10} and $PM_{2.5}$ in Ontario during air quality episodes showed that $PM_{2.5}$ composed about 73% of PM_{10} and that sulphate accounted for about 50% of $PM_{2.5}$. Trajectory analyses suggest that the movement of air pollutants over medium and long term distances is mainly from the United States and contributes to elevated sulphate and fine particulate matter recorded in southern Ontario.

- It is well documented that particulate matter and ozone cause adverse impacts on human health, vegetation and property. These impacts occur in Ontario, just as they do in the United States. For example, a study[4] published in 1994 involving 168 acute care hospitals in Ontario determined that hospital admissions due to respiratory effects increased by 5% when ozone levels increased by 50 parts per billion.

3.3 The International Context

Table 2 sets out a number of air quality limits for ozone in various countries around the world. It is evident that a number of countries have already adopted ozone standards, criteria or objectives more stringent than the existing United States standard. Moreover, 11 countries including Austria, Japan, New Zealand, Sweden, Switzerland, and the United Kingdom, have adopted an ozone objective of 80 ppb or less. The Canadian 1 hour ozone objective, already at 82 ppb, is currently under review and a new objective is anticipated in 1997 or 1998. Ontario's current ozone objective of 80 ppb will be adjusted accordingly to reflect the new Canadian objective.

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[4] Burnett, R.T., Dales, R.E.; Raizenne, M.E.; Krewski, D.; Summers, P.W.; Roberts, G.R.; Raad-Young, M.; Dann, T.; Brook, J. Effects of low ambient levels of ozone and sulphates on the frequency of respiratory admissions to Ontario hospitals. Environ Res 1994; 65: 172-194

The existing standard in the United States is a 1-hour average at 120 ppb. Analysis of ozone data from monitoring sites in the United States indicates that the proposed new standard of an 8-hour average concentration of 0.08 ppm (80 ppb-third highest) is comparable to a one-hour standard of about 0.10 ppm (100 ppb-second highest). Analysis of Ontario ozone monitoring results over the period from 1991-95 supports this finding. In Ontario, attainment of an eight hour average of 0.08 ppm would be the same as allowing about 20 exceedances per year of Ontario's existing 1 hour criterion of 80 ppb at each monitoring site. The number of exceedances would be even higher if the analysis had taken into account the rounding convention that applies to the U.S. standard (i.e. using 0.085 as opposed to 0.080 for the eight hour standard). Accordingly, the introduction of an eight hour average leads to significantly less protection than a one hour average. As a result, the proposed new standard of 0.08 ppm based on an 8-hour average remains less stringent than the limits for ozone already in place in many other countries. Moreover, the proposed new standard will be less stringent than the existing Canadian and Ontario ozone objectives.

In our submission, by adopting more stringent standards for ozone than those proposed, the United States will more closely reflect current standards already in place in most of the industrialized world. More stringent standards will provide Americans with a level of protection from ground-level ozone that has become increasingly accepted internationally. Over time, the lower standards will lead to lower loadings of our common airshed and result in lower levels of transboundary pollution in Ontario.

Few jurisdictions in the world have as yet adopted limits for particulate matter. Japan has set PM_{10} levels of 20 and 10 $\mu g/m^3$ for one and 24 hours, respectively. The United Kingdom has developed a standard for PM_{10} of 50 $\mu g/m^3$ on a 24 hour basis. The State of California has adopted more stringent standards than other American states, 50 and 30 $\mu g/m^3$ for 24 hours and one year, respectively. We are not aware of any jurisdiction which has developed specific standards for $PM_{2.5}$. However, Canada, Ontario and the other provinces are currently developing Canadian ambient air quality objectives for PM_{10} and $PM_{2.5}$. We anticipate that the objectives will be in place in 1997 or 1998.

In these circumstances, the United States has an opportunity to demonstrate leadership in environmental standard setting with respect to particulate matter. In our submission, the EPA should set more stringent standards for PM_{10} and $PM_{2.5}$ than it has proposed in order to provide appropriate protection to public health and the environment in the United States and to effect reductions in the transboundary movement of these pollutants. Again, the lower standards will lead to lower loadings of our common airshed and result in lower levels of transboundary pollution in Ontario.

Table 2 Ozone Ambient Air Quality Limits in Various Countries[5]

Country	Air Quality Limit ppb	Averaging Time
Austria	60	30 min
Canada Ontario	82 80*	1 hr 1 hr
Israel	115	30 min
Japan	60	1 hr
Kuwait	78	1 hr
Mexico	108	1 hr
Netherlands	60	1 hr
New Zealand	60	1 hr
Poland	50	30 min
Saudi Arabia	147	1 hr
South Africa	120	1 hr
Soviet Union	50	Not specified
Sweden	60	1 hr
Switzerland	60	1 hr
United Kingdom	50	Running 8 hr avg
United States	120**	1 hr

Note: Unless otherwise indicated, where values for a jurisdiction were given only in $\mu g/m^3$, the following conversion factor was used: 1 $\mu g/m^3 \approx 0.5$ ppb, based on normal conditions at 25°C and 760 mm Hg

* conversion from ppb to $\mu g/m^3$ based on 10°C and 760 mm Hg as per Ontario Regulation 337

** enforced at 125 ppb

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5 Journal of Air & Waste Management Association, 1992, page 1567; Chemosphere, 1993, page 1691; and Expert Panel on Air Quality Standards - United Kingdom, 1994

4. ONTARIO'S SCIENTIFIC ANALYSIS OF THE PROPOSED DECISIONS

4.1 Introduction

Ministry staff have reviewed the documentation associated with the U.S. Environmental Protection Agency ("EPA") announcement of November 27, 1996 pertaining to proposed decisions to be placed in the Federal Register regarding the revision of National Ambient Air Quality Standards (NAAQS) for both particulate matter (PM) and ground level ozone (O_3). The documentation reviewed for each pollutant included:

- Federal Register Documents
- Office of Air Quality Planning and Standards ("OAQPS") Staff Papers
- Air Quality Criteria Documents

Ministry staff have drawn a number of conclusions based on an assessment of the scientific evidence that was utilized.

Given the volume of scientific evidence that has been summarized by large teams of scientists working on the criteria documents and staff papers for each of these two major air quality contaminants over the past four to five years and considering the complexity of the exposure:response assessment studies associated with these regional air quality contaminants, Ontario's review of this material during the extended comment period was, of necessity, limited to major areas of support or concern with the proposed decisions.

Accordingly, scientific evidence and conclusions contained in or pertaining to the Federal Register proposed decisions that have not been specifically referred to in Ontario's submissions should not be taken to indicate support or opposition by Ontario.

Before reviewing the scientific basis of the regulatory limits, Ministry staff examined the U.S. EPA's underlying policy relating to the utilization of scientific evidence and the associated uncertainties in the development of standards designed to provide protection to human health and the environment. In this regard, the U.S. EPA has a clear and unambiguous policy based upon provisions of the Clean Air Act. It is described in the two OAQPS staff papers. The definition of Primary Standards is: "ambient air quality standards the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health".

The purpose for the margin of safety requirement is described in the Proposed Decisions as follows:

- the requirement for an adequate margin of safety for primary standards was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standards

setting; and

- the adequate margin of safety was also designed to provide a reasonable degree of protection against hazards that research has not yet identified.

Thus, by selecting science-based primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful, but also to prevent lower pollutant levels that she finds may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. The decision on an adequate margin of safety is a policy choice that is left specifically to the Administrator's judgment.

A Secondary Standard is defined as one that "shall specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air". Welfare effects include, but are not limited to effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property and hazards to transportation , as well as effects on economic values and on personal comfort and well-being.

The Ministry scientific review was undertaken in the context of the legal and policy framework noted above. The Ministry's submission on each of the proposed decisions is set out below.

4.2 Review of Proposed Decision on Particulate Matter

The EPA Administrator has proposed to maintain the current standard for PM_{10}, which includes particles 10 microns or less in size, and to add a new $PM_{2.5}$ category for particles at or less than 2.5 microns in size.

4.2.1 Summary of the Proposed Decision on PM_{10}

In the case of PM_{10}, the proposed decision is outlined in Table 3. The only departure from the existing standard relates to the 24 hour standard, where a move away from a concentration-based approach to a percentile exceedance approach is recommended. The only alternative that has been placed on the Federal Register is to revoke the 24 hour limit, leaving only the annual value of 50 $\mu g/m^3$.

Table 3 Particulate Matter - PM_{10}

Proposed Decision or Alternative	Averaging Time	EPA Proposed Decision and Alternative		Existing EPA NAAQS
		Value	Form	
Proposed Decision	24 hr	150 $\mu g/m^3$	98th percentile averaged over 3 years; using highest monitor in an area	150 $\mu g/m^3$ [Evaluated as: Allow 1 exceedance per year; 3 year avg.; highest monitor in an area]
	Annual	50 $\mu g/m^3$	Unchanged from existing [Evaluated as: Arithmetic mean; 3 year avg.; highest monitor in an area]	50 $\mu g/m^3$ [Evaluated as: Arithmetic mean; 3 year avg.; highest monitor in an area]
Alternative	24 hr	**Revoke** existing value of 150 $\mu g/m^3$		
	Annual	**Retain** existing value of 50 $\mu g/m^3$		

4.2.2 Factors Considered by the EPA in the Proposed Decision on PM_{10}

The staff paper[6] reviewed the scientific information and concluded that:

- the original quantitative basis for the level of the current 24 hr PM_{10} standard is no longer appropriate
- the new health studies and information on coarse particles do not provide a basis for a lower standard level
- a change to a more robust form (i.e. 98th percentile) of the standard is

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6 OAQPS Staff Paper, July 1996

required to better address the episodic nature of coarse particle excursions

- an annual standard will protect against the long- and short-term effects of coarse particles, such as aggravation of asthma, upper respiratory infections and bronchitis in children, as well as the long-term buildup of insoluble coarse fraction particles in the lung.

The OAQPS staff recommended the retention of the existing PM_{10} standard based on the following factors:

- fine and coarse fractions of PM_{10} should be considered as two separate pollutants;
- the results of the epidemiology studies provide ample reason to be concerned that there are detectable health effects attributable to PM at levels below the current standard for PM_{10};
- EPA staff believe that revision of the current standards is clearly appropriate;
- EPA staff note the larger body of epidemiological evidence and air quality information is related to undifferentiated PM_{10};

Based on these factors, OAQPS staff concluded that it was reasonable to consider two alternative approaches for revising the particulate matter standard:

1. Adopt more protective standards using PM_{10} as the sole indicator, combining fine and coarse fractions:
    - because the PM_{10} monitoring is in place, this option would result in more immediate implementation of revised standards
2. Develop separate standards for fine and coarse fractions of PM_{10} using appropriate indicators for each fraction:
    - because of the need to develop and install additional monitors, this approach would provide additional time to consider new scientific information before any such standards were actually implemented

In evaluating the two alternatives, the EPA examined the lessons learned from past Total Suspended Particulate (TSP) and PM_{10} programs:

- PM_{10} has been generally viewed as a local rather than a regional problem; in the eastern U.S. where regional levels of transported fine particles

make significant, but not dominant, contributions to PM_{10} mass, programs tend to focus on control of local sources, in part because of the difficulty in developing multi-jurisdictional strategies; abatement programs generally focus on the most readily available local sources of primary particles, leaving secondary or regional options as a last resort

- in areas where local fine particle sources are dominant (e.g. areas with high wood smoke contributions) PM_{10} controls have led to significant reductions in fine particles; historically, TSP-based local programs have also resulted in significant reductions in local primary fine particle emissions from coal combustion and industrial sources

- in areas where fugitive sources of crustal materials are clearly dominant, PM_{10} programs focus on measures that reduce road dust, construction and related sources; these programs have had limited success to date

- some areas (South Coast Air Basin, CA; Provo, UT,), having "mixed" contributions, including significant local secondary particle formation, have begun to require controls of gaseous precursors (SO_2, NOx) in addition to fugitive dust and other controls

- reductions in fine particles related to regional sulphur oxides emissions that have taken place are not related to implementation of the PM_{10} or TSP standards, but to the SO_2, NAAQS and the other mandated requirements of the Clean Air Act, such as the acid rain program

In examining the alternative of using PM_{10} as the sole surrogate for particles, the EPA staff noted that:

- selecting protective PM_{10} levels that would achieve proportional reductions of both PM_{10} and $PM_{2.5}$ in the East through a PM_{10} indicator alone would still result in significantly disproportional coarse particle control in the West;

Based on this analysis, OAQPS staff concluded that a decision to provide increased health protection through PM_{10} alone would have to be based on two additional premises:

1. Fine and coarse fraction particles are likely to produce similar health effects at equivalent concentrations, i.e. be of relatively comparable toxicity; and

2. Control strategies for fine and coarse fraction particles would produce roughly equivalent reductions in exposure in sensitive populations shown to be at increased risk of particulate matter effects.

EPA staff analysis could not support either premise.

Several other factors and conclusions emerged from the scientific analysis of the fine and coarse particle studies:

- Whatever the relative toxicity of fine and coarse fraction particles, based on the direct comparison of epidemiological studies and on exposure considerations, EPA staff concluded that control of sources of ambient fine particles is likely to be more effective in reducing exposure to sensitive sub-populations than is control of sources of ambient coarse fraction particles. Thus, given the available evidence, it concluded that a reduction in the level of the PM_{10} standard would provide effective health protection from the effects of the most harmful components of PM_{10}, but only at concentrations that appear to be unnecessarily stringent with respect to coarse fraction particles.

- It was recognized, however, that limited, but important epidemiological evidence suggests that coarse fraction particles are linked to effects in areas that exceed the current PM_{10} standard.

- Given the lack of evidence with respect to coarse particle effects at concentrations at or below the level of the current PM_{10} standards, however, little justification existed for proportional, much less disproportional reductions, in coarse fraction particles beyond those afforded by the current standards.

- Available evidence comparing the two fractions suggests that fine particles are a better surrogate for those components of PM_{10} that are associated with adverse effects at levels below the current standard;

For these reasons, EPA staff concluded that a single PM_{10} indicator would not provide the most effective and efficient protection from the health effects of particulate matter. Instead, the data in this rationale suggest that the most effective and efficient approach would be to control PM_{10} through separate standards for fine and coarse fraction particles.

4.2.3 Ontario's Position on PM_{10}

Ontario has no major concern with respect to the scientific evidence that has been reviewed and the conclusions drawn by EPA staff. However, several factors which are relevant to making the PM_{10} standard more stringent than proposed, and which do not appear to have been fully considered, include:

- Adsorbed metals and organics, although higher in concentration on the

fine fraction, may still be significant on the coarse fraction;

- The recent study in Anchorage, Alaska shows adverse effect associations with the coarse fraction. The study[7] is discussed in the Health Effects section of the staff paper, but does not appear to have been considered in the decision making;

- A very high level PM_{10} standard, in the absence of a TSP standard, with a general ratio of 0.5 for PM_{10}/TSP, would allow excessively high (i.e. ~ 300 $\mu g/m^3$) TSP levels in some areas.

In Ontario's submission, the fact that PM_{10} includes $PM_{2.5}$, which has significant health effects, is a sufficient reason to implement a lower standard for PM_{10}. To propose a $PM_{2.5}$ standard will require $PM_{2.5}$ monitoring data over many years. PM_{10} data now exists and can support a lower PM_{10} standard. Thus, while Ontario supports the EPA move to establish a regulatory limit on the fine $PM_{2.5}$ particles, we have serious concern regarding the relaxation of the PM_{10} standard via the proposed 98th percentile exceedance rule. In Ontario's view, there is compelling scientific evidence cited in the supporting criteria documents and staff paper to support a reduced value for an undifferentiated PM_{10} standard. EPA states that: "because the PM_{10} monitoring network is in place, using PM_{10} as the sole indicator would result in more immediate implementation of revised standards". This is particularly important when contrasted to the long period (up to 2003) for implementation of the new $PM_{2.5}$ standard.

Accordingly, Ontario urges the Administrator to give serious consideration to the implementation of a more stringent PM_{10} standard. This would achieve reductions in a shorter time period, using the present PM_{10} monitoring network. It would provide improved human health protection until the new $PM_{2.5}$ standard becomes effective.

Other factors that Ontario submits warrant more serious consideration and a more stringent interim PM_{10} standard include:

- although there is mounting evidence that the health effects are primarily associated with the $PM_{2.5}$ fraction, there is still a health signal associated with the coarse ($PM_{2.5-10}$) fraction

- there is a much larger body of data on the health effects of PM_{10} compared to $PM_{2.5}$; this data would have a limited role if the focus remains exclusively on $PM_{2.5}$.

Furthermore, Ontario urges the EPA to consider keeping the 24 hour PM_{10} standard in

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7 Gordian, M.E.; Ozkaynak, H.; Xue, J; Morris, S.S; Spengler, J.D. Particle air pollution and respiratory disease in Anchorage, Alaska. Environ Health Perspect 1996; 104: 290-297

some less conservative relation (i.e. less conservative than would be suggested by the $PM_{2.5}/PM_{10}$ ratios from ambient monitoring data) to the proposed $PM_{2.5}$ standards, but still more stringent than proposed, without leading to disproportional reductions in the coarse fraction. In this way, all of the above noted factors could be addressed.

4.2.4 Summary of the Proposed Decision on $PM_{2.5}$

In the case of $PM_{2.5}$, the Administrator's proposed decision and two alternatives are outlined in Table 4.

The proposed decision of 50 $\mu g/m^3$ for 24 hours represents a selection from the range of 20-65 $\mu g/m^3$ proposed by EPA staff. In the case of the annual mean, the proposed value of 15 $\mu g/m^3$ was selected from a recommended range of 12.5-20 $\mu g/m^3$.

The "Limited" policy response alternative reflects the view that places great weight on uncertainties and limitations in the database for PM health effects, while recognizing $PM_{2.5}$ as a component of air pollution that should be addressed through a NAAQS. The policy goal of this option, according to the EPA, would be to focus on better characterization of fine particle pollution, while facilitating additional research before initiating any possible major new regulatory programs designed to reduce risks to public health. EPA is soliciting comments on whether standards set at these levels are sufficient to protect the public from adverse PM effects with an adequate margin of safety.

The "Highly Precautionary" policy response alternative reflects the view that the new health evidence makes a compelling case for causality between fine particles and health effects. It places less weight on uncertainties in the health evidence, suggesting that the serious nature of potential health effects warrants greater protection. This approach would not only result in a new monitoring network and additional health effects research, but would likely result in major new regulatory programs. EPA is soliciting comment on whether the standards set at these levels are necessary to protect the public from adverse PM effects with an adequate margin of safety.

Table 4 Particulate Matter - $PM_{2.5}$

Proposed Decision or Alternative	Averaging Time	EPA's Proposed Decision and Alternatives		Existing NAAQS
		Value	Form	
Proposed Decision	24 hr	50 $\mu g/m^3$	3 year avg. of the 98th percentiles (of each year) of the 24 hr $PM_{2.5}$ concentrations; from highest monitor in an area;	None
	Annual	15 $\mu g/m^3$	3 year avg. of annual AM spatially avg. across an area: (i) Avg. 24 hr → quarterly means at each monitor; (ii) Avg. quarterly means → annual means at each monitor; (iii) Avg. across designated monitoring sites to obtain annual spatial mean for an area (iv) Average 3 years of annual spatial means	None
"Limited" policy response alternative	24 hr	65 $\mu g/m^3$	Same as for 50 $\mu g/m^3$ above	as above
	Annual	20 $\mu g/m^3$	Same as for 15 $\mu g/m^3$ above	as above
"Highly Precautionary" policy response alternative	24 hr	20-50 $\mu g/m^3$	Same as for 50 $\mu g/m^3$ above	as above
	Annual	12 $\mu g/m^3$	Same as for 15 $\mu g/m^3$ above	as above

4.2.5 Factors Considered by the EPA in the Proposed Decision on $PM_{2.5}$

The health effects literature was comprehensively reviewed and can be briefly summarized as follows:

- over 80 key epidemiological studies have been reviewed and demonstrate that there are adverse health impacts from particulates
- in the last 5 years alone, dozens of studies have shown consistent associations between particles in the air, daily deaths and hospital admissions; these associations are predominantly with fine ($PM_{2.5}$) particles

- daily mortality effect estimates reported for $PM_{2.5}$ fall within the range of approximately 3-6% increases in relative risk for a 25 $\mu g/m^3$ increase in 24-hour average $PM_{2.5}$ concentrations, for those cities with statistically positive associations

- there appears to be no human health threshold

- the principal welfare effect is an impact on visibility and haze

- from both the health and welfare effect point of view, there is compelling evidence to revise the NAAQS for particulate matter

The OAQPS staff approach for selecting the range of levels for consideration by the Administrator and their conclusions regarding the implications of choosing from either end of the range are summarized below.

THE 24 HOUR 20 - 65 $\mu g/m^3$ RANGE FOR $PM_{2.5}$

Derivation of the Upper End of the 24 Hour 20-65 $\mu g/m^3$ Range for $PM_{2.5}$

EPA staff concluded that an appropriate range of 24-hour $PM_{2.5}$ levels should result in reductions in health risks relative to the risks associated with the current PM_{10} standard. From the risk assessment in two cities, results estimated for the highest 24-hour $PM_{2.5}$ level suggest that it would result in some reduction in risks relative to the current PM_{10} standard (see Table 5 below). The amount of the reduction would vary from city to city.

It was EPA staff's judgment that consideration should be given to a $PM_{2.5}$ standard set below a level reflecting any type of "approximate equivalence" with the current PM_{10} NAAQS. Two approaches to "approximate equivalence" were considered:

- a $PM_{2.5}$ level of 65 $\mu g/m^3$. This is below the $PM_{2.5}$ level that corresponds, based on a national average ratio, to the current PM_{10} standard level of 150 $\mu g/m^3$ (i.e. a $PM_{2.5}$ level of approximately 75 $\mu g/m^3$). The variability in this ratio was recognized, and thus, there is no national "equivalent" level;

- a $PM_{2.5}$ standard level that would result in the same number of counties being in non-attainment as with the current PM_{10} standard. For this comparison the current form of the standard was used (not the proposed 98th percentile); a $PM_{2.5}$ level greater than 75 $\mu g/m^3$ but much less than 100 $\mu g/m^3$ is predicted to result in approximately the same number of non-attainment counties.

Table 5 EPA Staff Risk Assessment Results

County	Health Effects	Incidence Associated with Existing Air Quality levels (from OAQPS Staff Paper)	Incidence upon Attainment of the Current PM_{10} Standard (from Federal Register)	Reduction[1] in Excess[2] Morbidity Upon Attainment of Standard			
				Alternative Standards Annual $PM_{2.5}$ only		Alternative 24 hour $PM_{2.5}$ Standards in Combination with an Annual Standard of 20 $\mu g/m^3$	
				20 $\mu g/m^3$	15 $\mu g/m^3$	24 hour - 65 $\mu g/m^3$	24 hour - 25 $\mu g/m^3$
				Incidence Reduction	Incidence Reduction	Incidence Reduction	Incidence Reduction
Los Angeles County	Mortality	800-2920	400-1000	150	320	280	590
	Respiratory and Cardiac Hospital Admissions	1750	250-1600	250	540	480	1000
	Respiratory Symptoms in Children	62,000	23,000-58,000	11,000	22,000	20,000	37,000
Philadelphia County	Mortality	220-920	200-500		60	40	260
	Respiratory and Cardiac Hospital Admissions	440	70-450		70	50	320
	Respiratory Symptoms in Children	11,200-16,200	6000-15,000		2000	1000	8000

[1] from Federal Register

[2] incremental to the risk reduction associated with attainment of the current PM_{10} standard.

Based on this assessment, staff concluded that there is no clear point of "equivalence" and recommended bounding the upper end of the range below 75 $\mu g/m^3$, at approximately 65 $\mu g/m^3$.

Derivation of the Lower end of the 24 hour 20-65 $\mu g/m^3$ Range for $PM_{2.5}$

Epidemiological studies reporting statistically significant associations (mortality and hospital admissions) were conducted in areas in which the mean 24-hour $PM_{2.5}$ concentrations ranged from approximately 16-30 $\mu g/m^3$. These studies are relevant to considering a range for a standard, since such studies provide risk estimates for which there is greatest confidence around the mean of the air quality data.

Results from the quantitative risk assessment (Table 5) suggest a continuum of decreasing health risk with lower alternative $PM_{2.5}$ standards, within and likely below the range of 65 to 20 $\mu g/m^3$.

EPA staff believe that a standard should be set at a level sufficiently above estimated background levels. Estimated annual average $PM_{2.5}$ background levels range from about 2-5 $\mu g/m^3$ in the East and from about 1-4 $\mu g/m^3$ in the West. In the East, maximum annual 24-hour fine particle concentrations of 15-20 $\mu g/m^3$ are possible from background sources. Assessment of concentration-response relationships suggested consideration of possible thresholds at concentrations of 18 and 10 $\mu g/m^3$;

Taking the above into consideration, EPA staff recommended 20 $\mu g/m^3$ as the lower end of the range for consideration.

Implications of a $PM_{2.5}$ Standard in the lower end of the 24 hour 20-65 $\mu g/m^3$ Range

A standard set at the lower end (20 $\mu g/m^3$) would place significant weight on the consistency and coherence of the body of evidence as a whole, and on the results of quantitative analyses of concentration-response information and risks. EPA staff believe that a standard set at this level, while not likely to be risk-free, would be precautionary in nature in protecting against a full range of short-term effects.

Implications of a $PM_{2.5}$ Standard in the upper end of the 24 hour 20-65 $\mu g/m^3$ Range

A standard set at the upper end (65 $\mu g/m^3$) would give significant weight to both the qualitative and quantitative uncertainties inherent in the most recent epidemiological studies, and conversely, little weight to the quantitative assessment of the evidence and associated risks. Such a standard would likely provide some increased protection relative to the current standard. However, this is inconsistent with the earlier staff position acknowledging that, from the health point of view, there is compelling evidence to revise the NAAQS for particulate matter.

ANNUAL AVERAGE 12-20 $\mu g/m^3$ RANGE FOR $PM_{2.5}$

In general, EPA staff believe that an annual standard would have the effect of controlling air quality across the entire yearly distribution of 24-hour $PM_{2.5}$ concentrations to varying degrees. An annual standard set at an appropriate level could also provide protection from health effects associated with short-term exposures to $PM_{2.5}$.

Derivation of the Upper End of the Annual Average 12-20 $\mu g/m^3$ Range for $PM_{2.5}$

An annual $PM_{2.5}$ level of 25 $\mu g/m^3$ is estimated to result in approximately the same number of non-attainment counties as the current PM_{10} NAAQS. In EPA staff's judgment, consideration should be given to an annual $PM_{2.5}$ standard set below a level reflecting approximate equivalence with the current annual NAAQS. Thus, staff recommended consideration be given to bounding the upper end of the range below 25 $\mu g/m^3$, at approximately 20 $\mu g/m^3$.

Derivation of the Lower End of the Annual Average 12-20 $\mu g/m^3$ Range for $PM_{2.5}$

Based on the long-term mortality study used in the quantitative risk assessment (Pope et al.,1995)[8], a statistically significant association was observed across 151 cities in which the annual $PM_{2.5}$ concentrations ranged from about 9 - 34 $\mu g/m^3$. These concentrations are relevant in considering a range for an annual standard.

In examining the concentration-response relationships for long-term mortality from the Pope et al.(1995) study, possible concentration cut-points at which effects threshold may potentially exist were identified. The lowest cut-point was 12.5 $\mu g/m^3$.

The body of evidence from long-term exposure studies, together with results from the quantitative risk assessment (Table 5), suggests a continuum of decreasing risks with lower levels of alternative annual $PM_{2.5}$ standards. EPA notes that this extends below the range of 15 - 20 $\mu g/m^3$. Estimates of mortality incidences are appreciably lower, but not eliminated, in going from an annual $PM_{2.5}$ standard of 20 to 15 $\mu g/m^3$. For example, in Los Angeles County it has been estimated that moving to an annual $PM_{2.5}$ standard of 20 $\mu g/m^3$ results in about 150 fewer deaths on an annual basis compared to achieving the current PM_{10} standard. Moving to an annual 15 $\mu g/m^3$ standard results in 320 fewer deaths.

In taking into account the above observations, EPA staff reasoned that the lower end of a range of $PM_{2.5}$ levels for the Administrator to consider should be consistent with the lowest cut-point from the cited health studies (12.5 $\mu g/m^3$) Further, EPA staff concluded that the lower end is sufficiently above annual $PM_{2.5}$ background levels to serve as a meaningful standard.

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[8] Pope, C.A., III; Thun, M.J.; Namboodiri, M.M.; Dockery, D.W.; Evans, J.S.; Speizer, F.E.; Heath, C.W., Jr. (1995) Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. Am.J. Respir. Crit. Care Med. 151: 669-674.

Implications of a $PM_{2.5}$ Standard in the Lower End of Annual Average 12-20 $\mu g/m^3$ Range

A standard set at the lower end (12.5 $\mu g/m^3$) would place significant weight on the consistency and coherence of the body of evidence as a whole, and on the results of quantitative analyses of concentration:response information and risks.

EPA staff believe that an annual $PM_{2.5}$ standard set at this level, while not likely to be risk-free, would be precautionary in nature in protecting against long-term mortality effects and other long-term morbidity effects such as lung function decrements and doctor-diagnosed bronchitis in children.

Implications of a $PM_{2.5}$ Standard in the Upper End of Annual Average 12-20 $\mu g/m^3$ Range

A standard set at this level (20 $\mu g/m^3$) would give significant weight to both the qualitative and quantitative uncertainties inherent in the long-term epidemiological studies, and conversely, little weight to the quantitative assessment of the evidence and associated risks. Such a standard would likely provide some increased protection relative to the current standard. However, this appears inconsistent with the staff position that from a health point of view there is compelling evidence to revise the NAAQS for particulate matter.

4.2.6 Ontario's Position on $PM_{2.5}$

Ontario's review of the EPA science assessment and the recommendations contained in the EPA staff paper identified no major areas of concern with the selection or interpretation of these very compelling health impact studies.

Ontario agrees with the EPA staff in terms of the importance of selecting the lower end of the range of $PM_{2.5}$ standards as was recommended for consideration by the EPA Administrator. We also endorse the EPA staff assessment regarding the importance of a "precautionary approach" in view of the enormous amount of health impact data. Even the EPA's own health risk assessment (Table 5) clearly depicts a continuum of decreasing health risks with lower levels of $PM_{2.5}$. It is clear from Table 5 that the public health gains from an approach reflecting a more precautionary response (i.e. 12.0 $\mu g/m^3$ annual average and 20 - 25 $\mu g/m^3$ 24-hour average) would far outweigh the other options.

Finally, we submit that the Limited policy response alternative combination of a 20 $\mu g/m^3$, annual spatially averaged mean, and a 65 $\mu g/m^3$, 24-hour, 98th percentile $PM_{2.5}$ standard, is likely to be less stringent than the current particulate matter standards in terms of the numbers of counties predicted to be out of compliance. The Limited policy response alternative, together with the long phase-in period (completion of standard review, establishment of new samplers, determination of non-attainment, SIP plan submission and approval, etc.) would lead to a long delay and little reduction in public health risks over the next 5-8 years.

Accordingly, Ontario urges the Administrator to re-consider the proposed decision for the $PM_{2.5}$ standard. Ontario submits that the Administrator should implement a standard at the lower end of the science-based range of $PM_{2.5}$ recommended by the EPA staff. The science-based range recognizes the continuum of adverse health effects.

4.3 Review of Proposed Decision on Ozone

4.3.1 Summary of the Proposed Decision on Ozone

The Administrator has proposed a major change in the form of both the primary and secondary ozone standard. In the case of the primary standard, the proposed decision recommends moving to an eight hour averaging period from the existing one hour basis and decreasing the level from 0.12 to 0.08 ppm. The proposed decision also specifies an attainment form requirement (3 year average of the 3rd highest daily maximum eight hour value from the highest monitor in an area), and there are several attainment form alternatives offered for consideration. One alternative includes a range from the 2nd to the 5th highest eight hour average. Another alternative for comment pertains to the rounding convention currently in place. In this regard, comment is solicited regarding the existing rounding practice of enforcing the standard with a rounding precision of 0.005 ppm (i.e., for a 0.08 ppm standard, an exceedance occurs only at levels $\geq$0.085 ppm or $\geq$85 ppb). The three alternatives for the primary standard that have been proposed involve bracketing the proposed eight hour value of 0.08 (0.09 and 0.07 ppm) as well as leaving the existing one hour value of 0.12 in place. The proposed primary standard decision and alternatives are shown in Table 6.

Table 6 Ozone - Primary Standard

Proposed Decision or Option	Averaging Time	EPA Proposed Decision and Alternatives		Existing NAAQS
		Value	Form	
Proposed Decision	8 hr	0.08 ppm	3 year average of each of the annual 3rd highest daily maximum 8-hr average (ie. rolling avg.) ≤ 0.08 ppm; highest monitor in the area determines attainment;	0.12 ppm, 1-hr avg; no more than one day exceedance per year with hourly levels at or exceeding 0.12 ppm averaged over 3 years; highest monitor in an area determines attainment
			This proposal also takes comments on the range between the 2nd and 5th highest daily maxima;	
Alternative[a]	8 hr	0.09 ppm	3 year average, 3rd highest daily max. - as above	
Alternative	Retain current primary standard	Retain current primary standard	Retain current form (one day per year with hourly values exceeding 0.12 ppm averaged over 3 years)	
Alternative	8 hr	0.07 ppm	3 year average, 3rd highest daily max. - as above	

[a] EPA considers this proposal as roughly equivalent in level of protection as the current standard of 0.12 ppm, 1 hr avg.

In the case of the secondary standard, the proposed decision sets out two alternatives. One alternative provides for the retention of the new primary standard as the secondary standard, the current approach. Another alternative recommends a new exposure:response concept in standard setting, reflecting the cumulative response of plants to ground level ozone. The details related to the secondary standard are shown in Table 7.

Table 7 Ozone - Secondary Standard

Proposed Decision or Alternative	Averaging Time	EPA Proposed Decision and Alternatives		Existing NAAQS
		Value	Form	
Alternative	Identical to Proposed New Primary Standard set at 0.08 ppm for 8 hours	Identical to New Primary Standard	Identical to Primary Standard	Same as primary standard (i.e., 0.12 ppm) 1-hr avg; no more than one exceedance per year averaged over 3 years; highest monitor in an area determines attainment (comment also sought on whether a spatial scale should be incorporated, and if so, the size of the scale area)
Alternative	SUM06 Seasonal Standard	25 ppm-hour	Sum of hourly O^3 concentrations $\geq$ 0.06 ppm-hours cumulated over 12 hr/day (8 am-8 pm) during the consecutive period of maximum concentrations during the ozone season to be $\leq$ 25 ppm-hour	As above

4.3.2 Factors Considered by the EPA in the Proposed Decision on a Primary Ozone Standard

There is a significant body of information available since the last review showing clear evidence from human clinical studies that Ozone ("O_3") effects of concern are associated with 8-hour exposures tested at levels of 0.12, 0.10, and 0.08 ppm. This includes evidence of statistically significant responses at 6- to 8-hour exposures to the lowest concentration evaluated, 0.08 ppm O_3. These responses at moderate exertion levels include:

- lung function decrements (i.e., FEV_1 decrements),
- respiratory symptoms (e.g., cough, pain on deep inspiration),
- nonspecific bronchial responsiveness, and
- biochemical indicators of pulmonary inflammation.

Field studies (i.e., summer camp studies) provide evidence of similar functional and symptomatic effects at ambient O_3 exposures that are consistent with the clinical (chamber study)

findings. Laboratory animal studies provide supporting evidence of O_3-induced biochemical indicators of inflammation and functional changes.

As cited in the Federal Register, numerous epidemiological studies have reported excess hospital admissions and emergency department visits for respiratory causes (for asthmatic individuals and the general population) attributed primarily to ambient O_3 exposures. These include O_3 concentrations below the level of the current standard, with no discernible threshold at or below this level. Also, associations between ambient O_3 exposure in areas with very high O_3 levels and daily mortality have been suggested by some studies.

Special "at risk" groups have been identified: active children, outdoor workers, individuals having pre-existing respiratory disease (i.e. asthma, chronic obstructive lung disease)

Although 6 to 8 hour exposures to 0.08 ppm (in chamber studies involving human exposures) have greater impact than one hour exposures, the risk assessment that EPA conducted shows that reductions in risks from both short-term and prolonged exposures can be achieved through a standard with an averaging time of either 1 or 8 hours.

Taking the evidence into consideration, the EPA staff approach for selecting the range of levels (0.07 to 0.09 ppm) for consideration by the Administrator was based on the following:

- providing protection against health effects directly associated with both 1- to 3-hour and 6- to 8-hour exposures (e.g., lung function decrements, respiratory symptom, non-specified bronchial responsiveness and acute pulmonary inflammation)

- providing protection against the effect of increased hospital admissions

- utilizing quantitative risk assessments to provide insight as to the degree of protection afforded by alternative 8-hour standards for some of these effects.

Derivation of the 0.09 ppm (8 hr) Ozone Level

EPA staff noted that the primary range of lowest effect levels relevant to all the effects of concern identified above is 0.08 to 0.10 ppm. EPA staff believe that this range of effect levels does not necessarily reflect the presence of a threshold below which effects do not occur. Rather, it may reflect levels at which studies finding statistically significant effects of concern have been conducted.

Therefore, EPA staff believe that it is also important to consider the extent to which sensitive or "at-risk" populations are likely to experience exposures associated with these effects and to consider quantitative estimates, when available, of the risk to sensitive and "at-risk"

populations in terms of the estimated absolute numbers and percentages of the populations that are likely to experience adverse levels of these effects.

EPA staff note that 0.09 ppm is the highest level of an 8-hour standard that would reduce estimated exposures and risks of the "at-risk" populations sufficiently to provide some margin of safety. OAQPS staff note in the staff paper that these recommendations reflect consideration of previous advice from the Clean Air Scientific Advisory Committee ("CASAC") during the last review (1989) of the O_3 NAAQS. In that review, CASAC concluded that the existing 1-hour primary standard provided "little, if any, margin of safety" and that the upper end of the range of consideration for the 1-hour primary standard should be 0.12 ppm. Several members of the present CASAC Ozone NAAQS Review Panel felt that consideration should be given to a 1-hr standard level of 0.10 ppm in order to provide for an adequate margin of safety and to offer some health protection against 8-hour exposures of concern. This advice, as EPA staff note, provides support for considering 0.09 ppm rather than 0.10 ppm as the upper end of the range for an 8-hour standard, in that exposures associated with the 8-hour effects and risks for respiratory symptoms are greater when a 0.10 ppm 8-hr standard is just attained than when a 0.12 ppm 1-hr standard is just attained.

Both EPA staff and the present CASAC appear to acknowledge the fact that the 0.09 ppm, 8-hr standard proposal is roughly equivalent in level of protection to the current standard of 0.12 ppm, 1-hr NAAQS. The 1989 CASAC review of the current standard demonstrated "little if any margin of safety". Given the new health evidence since 1989 and the present exposure and risk estimates, a 0.09 ppm/ 8-hr standard should not be within the range for consideration because it provides little improvement in protection against health effects. In the $PM_{2.5}$ proposal, EPA staff noted that consideration should be given to a $PM_{2.5}$ standard set below a level reflecting any type of "approximate equivalence" with the current NAAQS. The alternative of a 0.09 ppm/8-hr proposal for ozone is inconsistent with that approach.

Derivation of the 0.07 ppm (8 hr) Ozone Level

In conducting the exposure and risk analysis of the 0.06 ppm level, EPA staff concluded that the risk of health effects of concern occurring was extremely low. In most cases, it would approach zero on a percentage basis although not necessarily in absolute numbers. Considering both the nature of the health effects involved and the very small percentage of the population that would be affected, EPA staff believe that a primary 8-hour standard with a level of 0.07 ppm could be judged to provide public health protection with an adequate margin of safety for these effects of concern.

EPA staff noted that a standard set at this level would be more precautionary than a standard set at the upper end of the range, in that it would provide increased protection from long-term exposures that may be associated with potentially more serious but uncertain chronic effects. Ministry staff have summarized the salient aspects of the exposure analysis and risk assessment that were undertaken by EPA staff.

Exposure Analysis

The purpose was to provide an estimate of the size of the "at-risk" population. The methodology consisted of:

- use of the pNEM/O_3 exposure model
- utilization of the current standard and proposed alternative 8-hour standards
- utilization of 1- and 5-expected exceedance-based forms to roughly bound exposure estimates for other concentration-based forms of the standard under consideration (e.g., the second and fifth-highest daily maximum 8-hour average O_3 concentration, averaged over a 3-year period)
- analysis of the general population and two "at-risk" populations: "outdoor children" and "outdoor workers";
- selection of nine representative U.S. urban areas which include a significant fraction of the U.S. urban population (41.7 million people; 3.1 million children);

The findings of these studies are summarized below:

- children who are active outdoors (3.1 million) appear to be the "at-risk" population group examined, with the highest percentage and number of individuals exposed to O_3 concentrations at and above levels where there is evidence of health effects, particularly for 8-hour average exposures to $O_3 \geq 0.08$ ppm at moderate exertion (Table 8).

TABLE 8 Exposure Analysis Results for Ozone : Percent and Absolute Number of Outdoor Children Exposed to 8-hour Average O_3 Concentrations While at Moderate Exertion.

Effect Basis	At Current 1-hr NAAQS of 0.12 ppm	At 0.10 ppm 1-hr level	At 0.09 ppm 8-hr level	At 0.08 ppm 8-hr level	At 0.07 ppm 8-hr level
Percentage of children exposed	1 - 21 %	< 3 %	3 - 7 %	0 - 1.3 %	< 0.1 %
Number of children exposed	31,000 - 651,000	< 93,000	93,000 - 217,000	up to 40,300	< 3,100

Risk Assessment

The objective of the risk assessment was to estimate the magnitude of the risks to population groups believed by EPA and CASAC to be at greatest risk, either due to increased exposures (i.e., outdoor children and outdoor workers) or to increased susceptibility (e.g., asthmatics).

The methodology consisted of developing risk estimates for:

i) several of the respiratory effects observed in controlled human exposure studies (i.e., lung function decrements - measured as changes in FEV_1 and moderate or severe pain on deep inspiration - PDI); these results are shown in Table 9;

ii) excess respiratory-related hospital admissions for a typical urban area (New York); these results are shown in Table 10;

The results of the risk assessment are summarized below:

i) Risk Estimates For Adverse Lung Function and Respiratory Symptom Responses

- the risk estimates for various % of FEV_1 reductions classified to be adverse and respiratory symptom responses (i.e., pain on deep inspiration) are shown in Table 9;

- EPA staff note that the group which was shown to experience the greatest exposure in the exposure analysis - outdoor children - also has the highest risk estimates (Table 9)

Ministry staff note that the range of multiple occurrences per year for lung function decrements are 4 - 9 for $FEV_1 \geq 15\%$ and 2 - 5 for $FEV_1 \geq 20\%$. This means that the absolute number of effects/symptoms deployed as a median value for a single occurrence can be determined by multiplying the numbers in the "number of children" columns by a range of 2 to 9. Thus, the upper bound of symptoms may be in the millions in some cases in the study area.

Table 9 **Percent and Actual Number of Outdoor Children Estimated to Experience Various Health Effects One or More Times per Year Associated with 8- and 1-hour Ozone Exposures Upon Attaining Alternative Standards - Aggregate Results for 9 Urban Areas - Total Number of Children Residing in the 9 Urban Areas was 3.1 Million. Only the median value of the estimates is shown.**

Alternative Standards		Pulmonary Function Decrements, $FEV_1 \geq 15\%$ Associated with 8-hour Exposures		Pulmonary Function Decrements, $FEV_1 \geq 20\%$ Associated with 8-hour Exposures		Moderate or Severe Pain on Deep Inspiration Associated with 1-hour Exposures	
Level	Averaging Time & Form	% of Children	Number of Children	% of Children	Number of Children	% of Children	Number of Children
0.12 ppm	1 hour, 1 expected exceedance per year	8.3	257,000	3.0	93,000	1.0	3,100
0.09 ppm	8-hour, 5 expected exceedance per year	9.5	295,000	3.8	111,800	1.3	40,300
	8-hour, 1 expected exceedances per year	7.7	239,000	2.7	83,700	0.9	27,900
0.08 ppm	8-hour, 5 expected exceedance per year	6.7	208,000	2.3	71,300	0.8	24,800
	8-hour, 1 expected exceedance per year	5.1	158,000	1.4	43,400	0.6	18,600
0.07 ppm	8-hour, 1 expected exceedance per year	3.0	93,000	1.4	12,400	0.3	9,300

ii) **Excess Respiratory Hospital Admissions**

Excess respiratory hospital admissions associated with attaining lower standards compared to "as is" air quality in New York city are shown in Table 10.

Table 10 Median Estimates of Excess Respiratory-Related Hospital Admissions for Asthmatic Individuals per Year, Attributable to O_3 Exposures for the New York City Area Using 1991 Data.

	"As is" Air Quality	Just attaining the current 0.12 ppm 1-hour standard, 1 expected exceedance per year	Attaining the 0.09 ppm, 8-hour standard, 1 expected exceedance per year	Attaining the 0.08 ppm, 8-hour standard, 1 expected exceedance standard per year	Attaining the 0.07 ppm, 8-hour standard, 1 expected exceedance standard per year
Median Estimate of Excess Respiratory Hospital Admissions	390	210	180	115	60

It is acknowledged in the Federal Register that, based on the risk analysis partially summarized in Table 9 above, within any given urban area, statistically significant reductions in exposure and risk associated with functional (i.e. FEV_1) and symptomatic effects (PDI) result from alternative 8-hour standards as the level changes from 0.09 ppm to 0.08 ppm to 0.07 ppm. These reductions represent differences of hundreds of thousands of times that children would likely experience such effects under the range of alternative standards. It is similarly acknowledged in the Federal Register that reductions in hospital admissions and emergency room visits for asthmatic individuals are estimated to occur (as shown in Table 10) with each change in the level of the standard from 0.09 ppm, to 0.08 ppm and down to 0.07 ppm.

Most of the analysis of these results in the Federal Register focuses on the percentage of children affected. Thus, differences between 1- and 5-expected exceedance-based forms of the standard standards appear in the Federal Register as modest. The focus on percentages may be the reason for CASAC's conclusions as noted by EPA in Footnote 7 (in the Federal Register):

> "With regard to these risk analyses, CASAC concluded 'that there is no 'bright line' which distinguishes any of the proposed standards (either the level or the number of allowable exceedances) as being significantly more protective of public health,' and noted that the differences in percent of outdoor children responding between the present standard and the most stringent standard 'are small and their ranges overlap for all health endpoints.' (Wolfe, 1995b). To address any apparent differences between EPA's and CASAC's conclusions, it is important to note that EPA's risk analysis report (Whitfield et al., 1996) makes clear that there are

> *statistically significant* differences in estimated risk for alternative standard levels; whether one judges the differences to be *significant* or *small* can depend on whether one focuses on *percentages*, as CASAC's letter did, or on *total numbers* of times that children or other at-risk individuals experience such effects. The overlap in the ranges of risk referred to in the CASAC letter reflect *differences among cities* used in EPA's risk analysis (e.g., air quality, exposure patterns, environmental factors), not *random uncertainties in risk estimates within any given city*. Thus, the fact that the ranges overlap does not mean that there are no real or statistically significant differences in protection among alternative standards."

The point is clear. A lower standard for ozone will provide increased health protection to a statistically significant number of people.

4.3.3 Factors Considered by the EPA in the Proposed Decision on a Secondary Ozone Standard

The derivation of the proposed decision regarding the implementation of a new form of a secondary standard based on the cumulative response of biological systems to ground level ozone has been assessed and described in all of the supporting scientific documentation. Of the three possible biologically oriented indices (AOT60, W126 and SUM06), the EPA staff have recommended the SUM06 as the index of choice based on several appropriate considerations dealing with biological relevance and the capability of the indices to provide biological protection in concert with a proposed new primary ozone standard.

In terms of the actual value proposed by the Administrator (25 ppm-hours), it is important to recognize that this value provides protection to only 50% of the species that were experimentally assessed at yield/biomass loss values of 10%. The economic benefits associated with achieving the SUM06 secondary standard also are presented and evaluated in conjunction with achieving compliance with a range of proposed primary standards. For the seven crops selected, the range in benefits from achieving two levels of a secondary standard (25 and 38 ppm-hours) in combination with the various proposed primary standards in 1990 dollars is summarized in Table 11.

Table 11 Estimates of Agricultural Benefits Associated with Proposed Primary and Secondary Standard Scenarios

Proposed and Alternative Primary Standards	Secondary Standard Scenario	Range in Benefits as Measured by the Regional Model Farm (RMF) Under a Modified Agricultural Policy (Millions of $ in 1990)
1 Exceedance of Existing Primary Standard (0.12 ppm 1-hour)	Secondary Standard = Primary Standard	80-230
	SUM06 of 25 ppm-hr	160-380
	SUM06 of 38 ppm-hr	60-120
1 Exceedance of Alternative 8-hour Primary Standard of 0.09 ppm	Secondary Standard = Primary Standard	190-590
	SUM06 of 25 ppm-hr	70-160
	SUM06 of 38 ppm-hr	20-30
1 Exceedance of Alternative 8-hour Primary Standard of 0.08 ppm	Secondary Standard = Primary Standard	350-1,200
	SUM06 of 25 ppm-hr	20-40
	SUM06 of 38 ppm-hr	1-3
1 Exceedance of Alternative 8-hour Primary Standard of 0.07 ppm	Secondary Standard = Primary Standard	470-1,800
	SUM06 of 25 ppm-hr	0
	SUM06 of 38 ppm-hr	0

Several important conclusions emerge from this assessment:

- if the secondary standard is set equal to the primary standard, then the economic benefits accruing to farm producers from attaining the primary standard increase dramatically with each more stringent 8-hour value.

- it is apparent that the range of SUM06 values recommended by OAQPS staff has a major impact on the benefits to farm producers under all scenarios; it is unfortunate that SUM06 values that would provide greater protection to farm crops (e.g. 75% of crops protected) were not considered, as the value of the economic benefits would have been greater than the values shown for 25 and 38 ppm-hours.

4.3.4 Ontario's Position on Ozone

Primary Standard

Ontario supports the EPA in its attempt to move in the right direction by replacing the current ozone standard. However, as expressed in the analysis of the EPA assessment, Ontario recommends that serious consideration be given to moving closer to the science findings which document significant adverse health effects at levels below the proposed decision of an 8 hour, 0.08 ppm primary standard.

Ontario is concerned about the selection of an 8-hour level of 0.09 ppm as the upper range alternative for consideration. This alternative, according to EPA, is roughly equivalent to the current 1-hour standard of 0.12 ppm. The 1989 CASAC Review Panel found "little, if any, margin of safety" with the current standard. In EPA's consideration of the $PM_{2.5}$ proposal, the approach was to select values which were below any type of 'approximate equivalence' with the current NAAQS. In the ozone proposal, this approach appears to be absent.

It must be emphasized that there is a continuum of risk reduction demonstrated by the EPA's own exposure and risk analysis, with decreasing levels of alternative ozone air quality levels. Ontario also stresses the importance of judging the results by focusing not on percentages (see Tables 8, 9 and 10) but, as EPA staff themselves have pointed out, on the total number of times that individuals, many of them children, experience such effects. These risk reductions do not stop at 0.08 ppm.

In view of these findings, Ontario submits that EPA should select the lower end (ie, the 2nd highest 8-hour average) of the range for a concentration-based form of the standard. Again, in contrast to the CASAC recommendations, there are significant differences (see Table 9) between the upper and lower end of the range in terms of health effects.

Finally, Ontario encourages the EPA to change its rounding convention. The EPA recognizes that the current rounding convention (0.005 ppm) directly results in less public health protection than that which would be associated with a convention that defined the smallest increment of 0.001 ppm to be above the level of the standard for the purposes of determining exceedances of the standard. Based on 1993-1995 air quality data, approximately 13 million more people live in areas for which the 0.001 ppm rounding convention would result in improvements in air quality as compared to the current rounding convention.

Secondary Standard

Ontario supports the alternative decision reached by U.S. scientists that a more biologically relevant cumulative index in the form of a SUM06 is appropriate, given the experimental studies conducted to date. However, we are concerned about the level

recommended in the OAQPS staff paper, and with the level of 25 ppm proposed by the EPA.

In our view, protection of ozone sensitive crop and native species to a 10% yield or biomass level based on dealing with only 50% of the experimentally studied species is inappropriate. This has even greater significance given the fact that the experimental programs focused only on a limited number of crops, chosen primarily because they represented the majority (about 75%) of the agricultural production in the U.S. This will result in continued economic loss for the growers of these and the many other crops that were not on the limited study list. At a minimum, consideration should be given to the protection of 75% of the experimentally evaluated crops at a 10% yield loss level. Ontario does not support setting the Secondary Standard at the Primary Standard level since there is no biological basis for this alternative.

5. CONCLUSIONS

Ontario respectfully submits, for the reasons set out above, that the United States Environmental Protection Agency should implement more stringent standards for particulate matter and ozone than those proposed. In our submission, choosing more stringent standards will reduce the amount of transboundary pollution that Ontario receives from the United States, contribute to an improvement in air quality in our common airshed, and provide enhanced protection for public health and the environment both in the United States and Ontario. The specific action requested with respect to each of the Proposed Decisions is set out below.

5.1 Proposed Decision on Particulate Matter Docket Number A-95-54

PM_{10}

Ontario respectfully requests that the United States Environmental Protection Agency adopt a more stringent standard for PM_{10} while efforts are underway to move to a $PM_{2.5}$ standard

$PM_{2.5}$

Ontario respectfully requests that the United States Environmental Protection Agency adopt a more stringent standard for $PM_{2.5}$, at the lower end of the range recommended by the Agency's scientists.

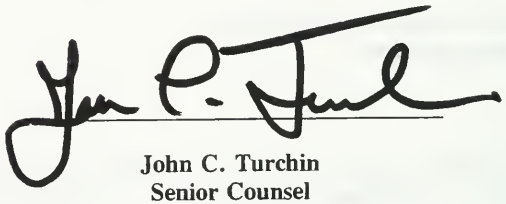
5.2 Proposed Decision on Ozone Docket Number A-95-58

Ontario respectfully requests that the United States Environmental Protection Agency adopt more stringent primary and secondary standards for ozone, implement a concentration-based form for the primary standard set at the lower end of the proposed range, and reduce the rounding convention from 0.005 to 0.001 ppm.

All of which is respectfully submitted.

Dated at Toronto, Ontario, Canada on March 6, 1997

Signed by legal counsel on behalf of
The Honourable Norman W. Sterling
Minister of Environment and Energy
Province of Ontario, Canada



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